



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 20 1999

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Scott G. Beach
8185 Walnut Fair Circle
Fair Oaks, CA 95628-2743

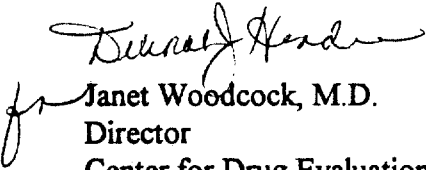
Re: Docket No. 99P-1149/CP1

Dear Mr. Beach:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition, dated April 19, 1999, requesting that the "WARNINGS" section of the labeling of Mintezol contain the following statement: "Mintezol use may cause threadworms (*Strongyloides stercoralis*) to migrate out of the user's body, thereby increasing the risk that the infection may be transmitted to other people."

This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely yours,


for Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

99P-1149

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